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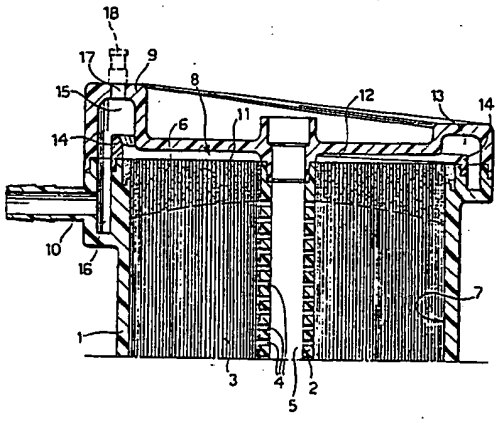
(54) Hollow-fibre oxygenation device.

(57) The device, which is intended for use in the oxygenation of blood, comprises a bundle of hollow fibres (3) for oxygen exchange, intended to carry a blood flow within them and to be flowed over by an oxygen-carrying flow (4). The bundle of fibres (3) is inserted in a casing (1) provided with shaped end part (9) which is intended to be oriented upwardly, in use, and which forms a collecting chamber (8) for the oxygenated blood. This shaped end part (9) includes at least one connector (10) for discharging the blood, which is situated in a position generally out of alignment with the path of propagation of any gas bubbles present within the collection chamber. The blood outlet chamber (8) is therefore shaped so as to constitute a trap for any bubbles present in the oxygenated blood.



EP 0 292 445 A1

Description

Hollow-fibre oxygenation device

The present invention relates to blood-oxygenation devices and concerns, in particular, a device comprising a bundle of hollow fibres for oxygen-exchange, the fibres being intended to carry a blood flow within them and to be flowed over by an oxygen-carrying flow, and a casing for containing the fibres, having a shaped end part (cap) which is intended to be oriented upwardly when the device is in use and which forms a collection chamber for the oxygenated blood which is open to the presence of bubbles, and has at least one blood-discharge connector.

Oxygenation devices of this type, which are preferably designed for use in a surgical environment for establishing blood circulation outside the body to maintain physiological levels of oxygen and carbon dioxide in the blood, are well know in the art.

The gas-exchange between the two phases, blood/oxygen-carrying flow, takes place through the semipermeable walls of the fibres and leads to enrichment of the blood with oxygen and the simultaneous removal of carbon dioxide therefrom.

Usually, in the devices in question, which are intended to be kept vertical during use, the blood flow to be oxygenated enters the device at the bottom and is discharged, after the oxygen exchange, from the top.

At least two different solutions are known in the art for the production of oxygenation devices, of the type specified above, in which the blood passes within the fibres.

According to the first solution, the device is constituted essentially by a tubular casing which surrounds the bundle of fibres and has two end parts forming respective manifolds, or inlet and outlet chambers, for the blood. Two generally discoidal sealing masses formed at the opposite ends of the bundle of fibres separate the two blood-collection chambers from the central cavity of the device itself. The flow of oxygen-carrying gas is circulated in the latter cavity, usually in the opposite direction (countercurrent) to the blood flow.

In the other solution (which is that which will be referred to in the detailed description of the invention below), the device has a tubular core which extends along the central axis of the fibre bundle. The wall of the core has holes through which the oxygen-carrying gas emerges, diffusing through the bundle of fibres in a generally radially direction thereof.

In both solutions, which provide for the passage of the blood within the fibres, a problem may arise due to the presence of air bubbles which have entered the blood-flow inadvertently, upstream of the oxgenation device or through the semipermeable walls of the fibres. There is a risk of these bubbles being drawn, with the oxygenated blood, into the patient's body, where they could result in the formation of embolisms or other dangerous ocurrences.

In order to avoid this problem, it is usual to provide an element which acts as a trap for the oxygen bubbles in series in the blood line which connects the output of the oxygenation device with the patient's body.

The object of the present invention is to provide a blood-oxygenation device in which the function of trapping or capturing any bubbles present in the blood is carried out, at least in part, within the oxygenator, making the extracorporeal circulation system simpler and less exacting, both structurally and in terms of bulk.

According to the present invention, this object is achieved by virtue of a blood-oxygenation device of the type specifed above, characterised in that the connector for discharging the blood is located in a position generally out of alignment with the path of propagation of the bubbles within the collecting chamber.

The collecting chamber preferably has a portion which is lowermost in use, the connector being situated in this lowermost portion.

The blood-collecting chamber usually has a shape which diverges overall towards a region of maximum vertical extent in its position of use, so that this region has an uppermost part in which the bubbles collect and a lowermost part in which the blood discharge connector is situated.

A vent duct for the bubbles may, to advantage, be provided in this uppermost region.

The invention will now be described purely by way of non-limiting example, with reference to the appended drawing which shows the end part of a hollow-fibre oxygenation device in axial section. This relates, specifically, to the end which is intended to be at the top in use.

According to a widely-known solution, the oxygenation device is constituted by a tubular casing 1 provided with a central core 2, which is also tubular, so as to define a space of circular-annular section in which a bundle of semi-permeable fibres 3 is disposed.

A blood flow passes through the cavities within the fibres 3, and, in the arrangement illustrated in the drawing, flows from the bottom upwards.

The wall of the central core 2 has a plurality of holes 4 through which a flow of oxygen-carrying gas, which reaches the interior of the central cavity 5 of the core 2 (by known means), can diffuse radially into the space containing the fibres 3 so as to flow over the surfaces of these fibres.

Gas exchange thus takes place between the blood and the oxygen-carrying flow through the semipermeable walls of the fibres 3 causing enrichment of the blood with oxygen and simultaneous removal of the carbon dioxide in the blood.

The device thus carries out a function wholly analogous to that usually fulfilled by the lungs. For this reason, devices of the type described are sometimes also known as "artificial lungs".

The upper ends of the fibres 3 are embedded in a sealing mass 6 of a material such as polyurethane or the like, but with the ends of the fibres left open.

Usually (also according to a widely-known solution) the ends of the fibres 3 are encased in the sealing mass 6 and then the resulting complex is cut. This removes the end portions of the fibres which may be blocked by the sealing material, enabling the blood which is circulated within the fibres 3 to flow through them freely. The main function of the sealing mass 6 is to separate the intermediate region of the device, indicated 7, into which the oxygen-carrying gas diffuses from the central core 2, from two end chambers which constitute manifolds for collecting the blood to be oxygenated and the oxygenated blood.

The drawing shows only the end chamber 8 which collects the oxygenated blood discharged vertically from the fibres 3.

The chamber 8 is defined by a shaped end part 9 of the casing 1. The part 9 is generally known in the art as the "cap".

The end part 9 has at least one connector 10 through which the oxygenated blood which collects in the chamber 8 can be returned to the patient's body.

The chamber 8 is defined by the internal surface of the cap 9 which is generally annular in shape as well as by the end plate 11 which faces the end openings of the fibres 3.

More precisely, the chamber 8 can be seen to include:

a radially inner portion 12 of small, constant height (measured axially of the device, that is in the direction in which the fibres 3 extend) (of the order of a mm), and

a radially outer portion 13 of greater height, ideally surrounding the edge of the end plane 11 of the bundle of fibres 3, which is bounded by a deflector element 14.

The heights of both the peripheral portion 13 of the chamber 8 defined by the cap 9 and of the deflector element 14 which is fixed to the end edge of the central part of the casing 1, (still measured axially of the device) increase gradually towards the zone in which the connector 10 is situated.

More particularly, in the zone furthest from the connector 10, the height of the deflector element 14 corresponds approximately to the height of the inner portion 12 of the chamber 8. The height of the deflector element reaches its maximum in the region in which the connector 10 is situated. The height of chamber 8 reaches its maximum extent, axially of the device, in this same region.

In this region, the chamber 8 therefore has an uppermostpart 15 and a lowermost part 16. The connector 10 is located in this lowermost part, which is generally below the end plane 11 of the bundle of fibres.

An aperture 17 is, on the other hand, provided in the uppermost part 15 of the chamber 8 in the wall of the cap 9, and a vent device 18 can be inserted therein.

In operation, the oxygenation device according to the invention is kept in the vertical position, that is, in a position which corresponds, in practice, to that illustrated in Figure 1.

The oxygenated blood emerges vertically from the fibres 3 and collects in the radially-inner portion 12 of the chamber 8.

Moving generally radially of the core 2, the oxygenated blood then spreads out towards the radially-outer region 13 of the chamber 8. In this movement, the blood encounters the deflector element 14 which deflects the flow upwards.

The blood which collects in the region 13, around the entire periphery of the chamber 8, tends to flow towards the outlet connector 10, that is towards the peripheral region of the cap 9 in which the uppermost part 15 and the lowermost part 16, and hence the connector 10, are situated.

This movement is facilitated by the fact that the chamber 8 (or, more precisely, its radially-outer portion 13) has dimensions which increase gradually towards the region in which the uppermost part 15 and the lowermost part 16 are situated.

The result of this shape of the chamber 9 is that any air bubbles present in the oxygenated blood tend to collect towards the uppermost part 15, whilst the blood flows towards the lowermost part 16 where the connector 10 is situated.

Thus, the uppermost part 15 acts as a trap for any bubbles in the oxygenated blood.

The bubbles which collect in the uppermost part 15 may be removed through the vent device 18 connected to the aperture 17.

The device 18 may, for example, be connected through a blood-flow line to the reserve and filtration unit (cardiotome) which is normally connected to the oxygenation device. This unit (not illustrated in the drawing), collects blood in the operating area through one or more intake lines and filters from it any fragments of extraneous material or air bubbles. The blood, thus purified, can then be recycled to the inlet of the oxygenator. The line which connects the vent device 18 to the cardiotome is thus a line which partially recycles the blood output by the oxygenator. The line may always be open and, in this case, a small proportion of the blood is recycled taking with it any bubbles which have collected, or may be opened only intermittently when there is a need to eliminate a bubble.

Claims

1. A blood-oxygenation device comprising a bundle of hollow fibres (3) for carrying a blood flow within them and intended to be flowed over by an oxygen-carrying flow (4), and a casing (1) for containing the fibres (3), having a shaped end part (9) which is intended to be oriented upwardly in use and which forms a collecting chamber (8) for the oxygenated blood which is open to the presence of bubbles, and has at least one blood-discharge connector (10), characterised in that the blood-discharge connector (10) is located in a position generally out of alignment with the path of propagation of the bubbles within the collecting chamber (8).

2. A device according to Claim 1; charac-

terised in that the collecting chamber (8) has a part (16) which is lowermost in use and in that the connector (10) is located in this lowermost part (16).

3. A device according to Claim 1 or Claim 2, characterised in that the collecting chamber (8) has a shape which diverges overall towards a region (15, 16) of maximum vertical extent, in its position of use, so that the region of maximum vertical extent has an uppermost part (15) and a lowermost part (16) and in that the connector (10) is located in the lowermost part.

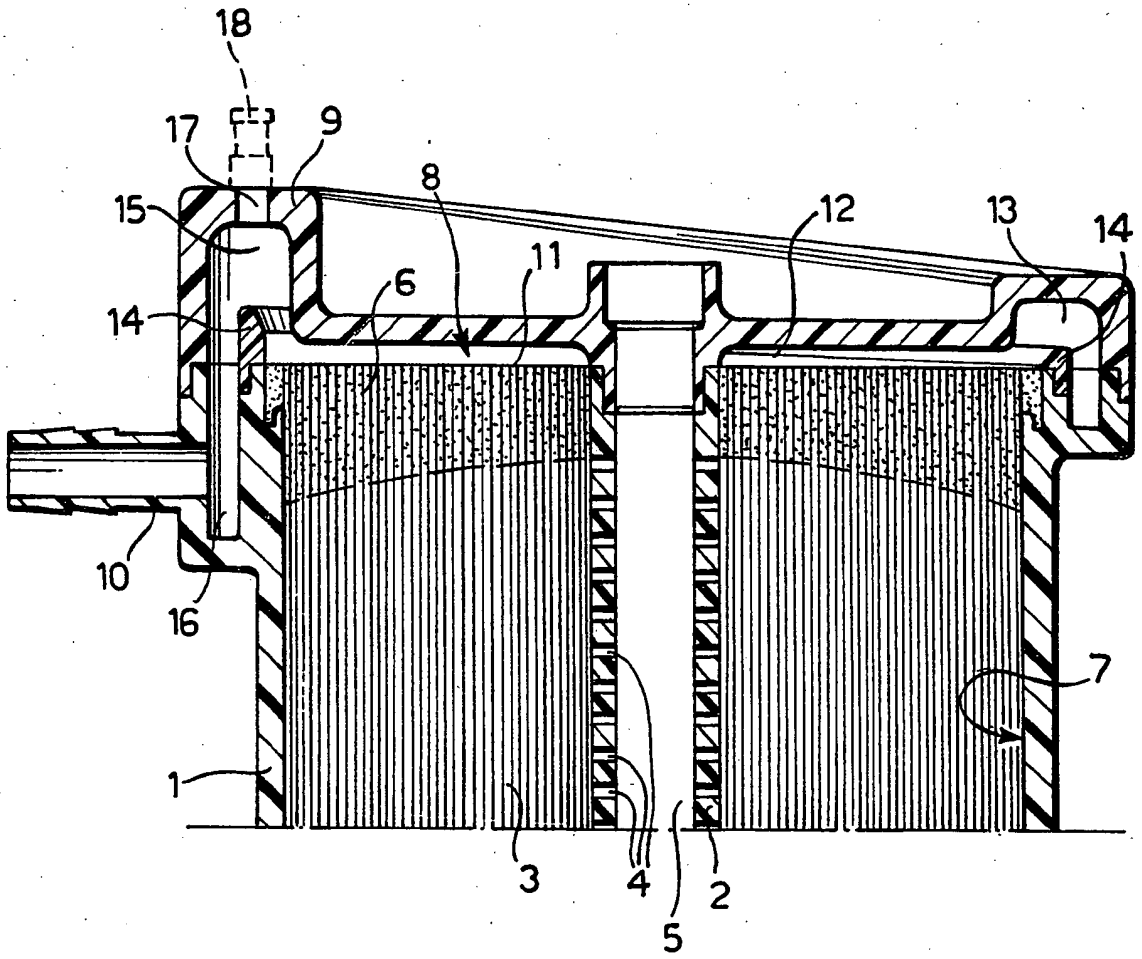
4. A device according to Claim 3, characterised in that it includes a vent duct for the bubbles (17, 18) located in the uppermost part (15).

5. A device according to any one of Claims 1 to 4, characterised in that the bundle of fibres (3) has an end plane (11) delimiting the blood collecting chamber (8) and intended to face upwardly in use, and in that the connector (10) is situated in a position generally below the end plane (11).

6. A device according to one of Claims 1 to 5, characterised in that the bundle of fibres (3) has an end plane (11) delimiting the blood collecting chamber (8) and intended to face upwardly, in use and in that the end plane (11) is surrounded by a deflector element (14) which projects relative to the end plane (11).

7. A device according to Claim 6, characterised in that the projection of the deflector element (14) from the end plane (11) increases towards the blood discharge connector (10).

8. A device according to any one of the preceding claims, characterised in that the blood collecting chamber (8) is generally annular in shape with a radially inner portion (12) of substantially constant height, and a radially outer portion (13) whose height increases gradually towards the blood discharge connector (10).



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EUROPEAN SEARCH REPORT

Application Number

EP 88 83 0214

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	EP-A-0 114 732 (AMERICAN BENTLEY INC.) * Figures 1,4-6; page 9, lines 1-13; page 13, lines 3-16 *	1	A 61 M 1/18 B 01 D 13/01
Y	---	2-4	
Y	EP-A-0 103 899 (TERUMO) * Figures 8,15-18; page 23, lines 6-20; page 49, lines 19-23; page 50, line 26 - page 51, line 3 *	2-4	
A	---		
	US-A-4 368 118 (SIPOSS) * Figures 4-5; column 3, lines 7-30; column 3, line 65 - column 4, line 39 *	5-6	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

B 01 D
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	25-08-1988	JONES T.M.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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